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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,917	01/25/2002	Raj Chakrabarti	PU-0034	3743

7590 09/02/2004

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,917

Applicant(s)

CHAKRABARTI ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,15-30,60-63 and 67-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,15-30,60-63 and 67-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action and amendment filed on May 10, 2004 has been entered.
2. Claims 4, 6-14, 31-59, 64-66 are cancelled. Claim 1 and 60 are amended. Claims 1-3, 5, 15-30, 60-63, 67-70 are pending.
3. The instant application has filing date as January 25, 2002 and claims priority to provisional applications 60/264,935 filed on 1/30/2001, 60/298,166 filed on 6/14/2001 and 60/298,250 filed on 6/14/2001.

Response to Arguments

4. Applicants' response to arguments and amendment have been entered and found persuasive in part.
5. With reference to the rejection made under 35 USC 112, first and second paragraphs, Applicant's arguments have been fully considered and the rejection is withdrawn in view of the arguments.

6. The following is the rejection made in the previous office action under 35 USC 103(a):

Claims 1, 2-3, 5, 15-30, 60-63, and 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segev (USPN. 6,348,583) in view of Cheng (USPN. 5,512,462).

Segev teaches a compound (poly(ether-sulfoxide)) (adjuvant or cosolvent) comprising the formula of claims 1, 15, 60, and 67, wherein Segev teaches that the formula comprises R₁ as S; R₂ as H or CH₃; R₃ as C; and R₄, R₅ and R₆ as alkoxy or alkyl of length m, wherein m is between 2 and 8 (see column 7, lines 38, 43, column 8, lines 42-43, referring the second formula structure, column 19, lines 56-67 referring formula structure);

Segev also teaches with regard to claim 2-3, 16-18, that the compound form a cyclic structure involving 5 carbon members (see column 8, lines 42-43 and structure, wherein a nucleobase group (purine or pyrimidine having cyclic structure is linked) (see column 9, lines 14-22) or a heterocyclic group is linked (see column 20, lines 50-56);

With regard to claim 20-21, Segev teaches that the compound is acyclic (see column 19, lines 56-67);

Segev teach that the compound could be used in PCR reaction, primer extension and sequencing (see column 25, lines 10-23), however Segev did not teach the PCR composition comprising a buffer, one or more template polynucleotides, nucleotide triphosphates (dNTPs), one or more polymerase enzymes.

Cheng teaches a PCR reaction composition of claims 1, 23-30, 60-63, 67-70, comprising (i) template DNA, dNTPs, a DNA polymerase (which include Tth DNA polymerase, Tli DNA polymerase) and buffer with cosolvents (see column 7, lines 65-67, column 8, lines 1-63, column 9, lines 1-67); (ii) cosolvents include glycerol, dimethylsulfoxide (DMSO), polyethylene glycol (see column 8, lines 65-67, column 9, lines 1-6); (iii) a kit comprising PCR reaction mixture along with cosolvents (DMSO, glycerol) (see column 36, lines 47-52); (iv) DMSO at a concentration of 0.5%- 5% (v/v) (see column 9, lines 26-41).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified and improved the use of the adjuvant or cosolvent of Segev with the inclusion of PCR components of Cheng in order to achieve a sensitive and enhanced PCR composition as a whole. An ordinary practioner would have been motivated to add the PCR components because Cheng taught that use of cosolvents influence the

efficiency of amplification of the template by increasing the thermal stability of the DNA polymerase and reduces the loss of DNA polymerase activity during repeated high-temperature denaturation steps (see column 9, lines 2-7). Therefore, an ordinary artisan would have been clearly motivated to have modified the compound taught by Segev with the addition of PCR components to achieve efficient and improved PCR system.

Response to arguments:

With reference to the rejection made under 35 USC 103(a), Applicant's arguments have been fully considered and found not persuasive. Applicants' argue that that the instant claims are not obvious over Segev in view of Cheng and assert that Segev teaches nucleotide mimetic compounds and Cheng does teach use of cosolvents such as DMSO and glycerol to influence amplification. Applicants argue that the combination of the references would not make the instant claims obvious. In response to applicant's argument the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In the instant case, Seveg teaches the inventive compound, which can be, used in PCR reaction, primer extension and sequencing reactions (see col. 25, lines 10-23). Cheng teaches a PCR composition which includes all the reagents used in PCR amplification and cosolvents used in PCR reaction which influence the efficiency of the PCR reaction. It is prima facie obvious to one ordinary skill in the art to

combine the compounds which mimic cosolvents with PCR composition to achieve the benefit of stabilizing the PCR reaction. Thus the rejection is maintained herein.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprasanna Chunduru
August 31, 2004


JEFFREY FREDMAN
PRIMARY EXAMINER
